



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-23-22CX]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled "Preferences for Longer-Acting Preexposure Prophylaxis (PrEP) Methods Among Persons in US Populations at Highest Need: A Discrete Choice Experiment" to the Office of Management and Budget (OMB) for review and approval. CDC previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on March 2, 2022, to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

- (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

- (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- (c) Enhance the quality, utility, and clarity of the information to be collected;
- (d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and
- (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

Preferences for Longer-Acting Preexposure Prophylaxis (PrEP) Methods Among Persons in US Populations at Highest Need: A Discrete Choice Experiment - New - National Center for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The 2022-2025 National HIV/AIDS Strategy includes a goal of increasing PrEP coverage to 50% among persons with indications, from a 2017 baseline of 13.2%. Despite successes in development and scale up of daily oral pre-exposure prophylaxis (PrEP) as a biomedical HIV prevention product, studies consistently show obstacles to its uptake and continuation. The Centers for Disease Control and Prevention (CDC) and its partners must engage in early planning for the implementation of longer-acting (LA)-PrEP agents to help achieve the U.S. Ending the HIV Epidemic (EHE) goal of reducing incident HIV infections by 90% by 2030. Understanding providers' and priority populations' preferences for different LA-PrEP agents and perceived advantages and disadvantages of each product will be critical to estimating future uptake and market share of the various products that are likely to come to market.

The goal of this study is to understand preferences for long-acting pre-exposure prophylaxis (LA-PrEP) products for HIV prevention among potential users and providers, including

product characteristics and other service delivery factors that may facilitate or hinder future uptake of these products. RTI will collaborate with CDC to conduct a discrete choice experiment (DCE) among providers and potential users of LA-PrEP products to elicit their preferences for characteristics of LA-PrEP and delivery programs to maximize uptake of LA-PrEP among people in need of HIV prevention methods. Results from this experiment will be used to identify factors key to adoption and implementation of each product and increase implementation efficiency by identifying strategies to support decision making and address potential use challenges early on.

The study design is a cross-sectional, online survey comprised of a DCE and additional questions to directly elicit participant preferences and gather data on socioeconomic, behavioral, and attitudinal factors. DCE methods are based on the principle that products or services are evaluated through their multiple features or 'attributes,' and that an individual's choice of a product or service is a function of the utility of each attribute option or 'level.' Attributes and their corresponding levels are chosen to represent the features of medications, devices, and health care services that are relevant to a health care decision.

The proposed information collection will include two separate DCE surveys: one for priority populations; and one for clinicians. The survey uses an experimental design to combine levels from each attribute into hypothetical product profiles

and to pair profiles into choice tasks. The experimental design will be split into several blocks or versions. Each equally sized block will have 11 questions, with one question being repeated across blocks. Participants will be randomly assigned to a block and will see only one block when completing the survey instrument.

The study's target population includes clinical providers ages 18 and older who prescribe PrEP and the following priority population groups who were selected because they have the highest rates of HIV acquisition and are in need for HIV prevention services. To be eligible for the study, potential participants in each of the priority population groups must be 18 years of age and older, living without HIV, and meet the U.S. Public Health Service (USPHS) indications for offering PrEP as described in the 2021 USPHS Clinical Practice Guidelines.

The study sample will be recruited from cities with high numbers of annual HIV diagnoses within the 57 priority jurisdictions identified as part of the Ending the HIV Epidemic (EHE) initiative. Data collection will last approximately six months. Participants will be randomly assigned to a block when they are sent their unique DCE survey link and will only complete the set of choice tasks in that block. Throughout the study, we will closely monitor recruitment and data collection to ensure that screening criteria are being met, key demographic groups are adequately represented, and survey completion rates are acceptable. Participants will be reimbursed \$20 upon

completion of the DCE. A Visa gift card will be sent electronically or mailed via the postal system based on the participant's choice.

Participation is voluntary. For this study, CDC intends to screen approximately 9,200 participants and enroll 1,840. CDC estimates that approximately 15% of enrolled participants will be removed from the analysis due to fraud or incomplete data, resulting in a final analysis sample size of 1,600 participants. At 25 minutes per survey and 10 minutes per combined screener and consent, CDC requests OMB approval for an estimated 2,282 annualized burden hours. There are no costs to participants other than their time.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in Hours)
Potential LA-PrEP users or Clients	Client Screening Survey & Consent Form	8,050	1	10/60
	C4P Client DCE Survey	1,610	1	25/60
Clinical providers who prescribe PrEP, in the United States	Provider Screening Survey & Consent Form	1,150	1	10/60
	C4P Provider DCE Survey	230	1	20/60

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